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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/726,093

Applicant(s)

Fuchs et al.

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Apr 19, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 57-62, 64-71, 75-82, 96-98, 100-106, 110, 112, 113, 115, 117-122, 127, 128, 130-133 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 57-62, 64-71, 75-82, 96-98, 100-106, 110, 112, 113, 115, 117-122, 127, 128, 130-133 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on Apr 19, 2002 is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

Applicants' arguments, filed 4/19/02, have been fully considered but they are not persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Regrettably, some of these rejections were not found withdrawn earlier and some are the result of reconsideration of required elements of certain apparatus. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The presently pending claims include apparatus, method, and kit claims whereas only methods and kits are cited in the present title.

NEW MATTER

Claims 69, 120-122, 128, and 131 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Consideration of the electrical connection limitations of claim 69 has failed to reveal written basis for two elements of this claim. Firstly, the cited support on pages 28 and 29 lack

the written basis for such electrical connections in the apparatus of claim 58 with a plurality of channels. It is noted that claim 69 ultimately depends from claim 58. Secondly, the electrical connection of the detection zone to both each capillary channel and the ground has not been found. The closest disclosure is that of page 28, lines 9-15, wherein various voltages are applied to the elements depicted in Figure 13. The various zones of Figure 13 are described in the bridging paragraph between pages 27 and 28 but none of them are a detection zone for electrical connections as required in claim 69. It is noted that electrical connection is not described regarding a detection zone on page 29, lines 27-30. Thus, these claim 69 limitations are NEW MATTER.

Claims 120, 128, and 131 contain NEW MATTER which has not been found as filed regarding intersection of injection and electroseparation channels. Claims 121 and 122 have been and are included in this rejection due to their dependence from claim 120, thus also containing the above NEW MATTER. Applicants argue that Figures 12-14 show intersecting injection and electroseparation channels. In response these Figures show injection channels that each abut to an electroseparation channel and do not show intersection.

PRIOR ART REJECTIONS

The following is a quotation of the appropriate paragraphs

of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57, 96-98, 110, 115, 127, 128, and 130-133 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Rose (Anal. Chem. 65:3545 [1993]).

Regrettably, upon reconsideration the above instant claims are now rejected based on Rose. The Rose apparatus is disclosed on page 3546 as a capillary electrophoresis apparatus which contains separation gel medium and is loaded with various samples. The apparatus must inherently contain some type of sample introduction or injection zone as required in the instant claims or sample could not be introduced into the column as described on page 3546, second full paragraph of the lefthand column. This communication for sample introduction also discloses the generic intersection of instant claim 128. The presence of an incubation zone is included via the thermostating of the column as noted in the first full paragraph on page 3546, lefthand column. Such thermostating is disclosure of holding the temperature or incubating the sample at the thermostated temperature. Lastly, the PNA probe is deemed labeled in that 260 nm detection is utilized in the apparatus. This label is

internal but yet deemed a detectable label. Thus, the 260 nm absorbing nucleobases in the PNA is a type of label as instantly claimed. These disclosures anticipate instant claims 57, 115, 130, and 132. Instant claims 96 and 97 are anticipated by the buffer disclosure in Rose on page 3546, first full paragraph, lefthand column, as being of low ionic strength with only Tris-phosphate and 75 mM and 10% methanol which is an organic solvent. This is also a denaturing medium as required in instant claim 133 because only the complementary polymers hybridize appropriately as depicted in the detected results in Figures 2, 3, 5, and 7. Claim 98 is anticipated by the charge-modifying disclosure for the PNA probes in the paragraph which bridges the left and righthand columns on page 3546 of Rose. Instant claim 110 is also anticipated by the detector inclusion in the apparatus as disclosed in Rose on page 3546, first full paragraph of the lefthand column. Taken as a whole, Rose utilizes the above noted apparatus in a method of separation of DNA containing samples as in instant claim 127.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 58, 59, 61, 62, 64, 67, 68, and 71 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rose in view of the legal decision of *In re Harza* [274 F.2d 669, 124 USPQ 378 (CCPA 1960)].

The legal decision of *In re Harza* is herein cited from the MPEP at section 2144.04, part VI B, directed to the obviousness of duplication of parts. Claims 58-62, 64, 67, 68, and 71 are directed to the apparatus as rejected over Rose above as anticipated except that they are duplicated with a plurality of the apparatus elements. Said legal decision indicates that such duplication of parts is an obvious variant over the single element disclosure.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to duplicate parts as in Rose as suggested as an obvious variant via the legal decision of *In re Harza*.

Claims 57-62, 64-68, 70, 71, 75-82, 96-98, 100-106, 110,

112, 113, 115, 117-122, 127, 128, and 130-133 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rose, taken in view of the legal decision of *In re Harza* regarding plural capillary apparati in certain instant claims, and taken further regarding Cummins et al. (P/N 6,045,995) for various PNA label embodiments as well as Nielsen et al. (P/N 5,539,082) for other labels on PNA probes.

The combination of Rose and the legal decision of *In re Harza* has been described above, but lacks the description of labels on the PNA probes such as fluorescein etc. as instantly claimed as well as electrophoretic media such as polyacrylamide gel, as well as the favoring of PNA complexes with target over DNA/DNA or DNA/RNA hybridization, as well as laser-fluorescence detection.

Cummins et al. also is a reference directed to capillary electrophoresis for the analysis of PNA/DNA hybridization. The probes of Cummins et al. are additionally described as being labeled with a variety of labels such as fluorescein etc. in column 3, lines 18-37, and in column 9, lines 3-55. The polyacrylamide gel capillary electrophoretic medium is described in column 3, lines 55-59. These probes may be preferably of the PNA type as described in column 8, lines 54-67. The PNA probe hybridization to target nucleic acid being favored over DNA/DNA or DNA/RNA hybridization for electrophoretic separation and

detection of hybrids is described in Cummins et al. in column 13, lines 12-25. Cummins et al. also describes laser-fluorescence detection in Example 7 in columns 15-16.

Nielsen et al. expands on Cummins et al. as summarizing other PNA probe labels including enzymes and biotin in column 9, lines 12-30.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the Rose apparatus and methods either singly or in a plurality element apparatus as suggested by *In re Harza* with capillary gels of polyacrylamide, various PNA probe labels, and with PNA probe containing hybrids favored over DNA/DNA or DNA/RNA hybrids, as well as laser-fluorescence detection, as set forth in Cummins et al. and Nielsen et al. to result in the practice of the instant invention.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)305-3014 or (703)308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 26, 2002

Ardin H Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER